0471S.05S

CONFERENCE COMMITTEE SUBSTITUTE

FOR

HOUSE COMMITTEE SUBSTITUTE

FOR

SENATE COMMITTEE SUBSTITUTE

FOR

SENATE BILL NO. 139

AN ACT

To repeal sections 208.227, 208.790, 208.798, and 334.506, RSMo, and to enact in lieu thereof eight new sections relating to health care.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF MISSOURI, AS FOLLOWS:

Section A. Sections 208.227, 208.790, 208.798, and 334.506, RSMo, are repealed and eight new sections enacted in lieu thereof, to be known as sections 196.990, 208.227, 208.229, 208.790, 208.798, 334.506, 338.700, and 338.710, to read as follows:

196.990. 1. As used in this section, the following terms shall mean:

(1) "Administer", the direct application of an epinephrine auto-injector to the body of an individual;

(2) "Authorized entity", any entity or organization at or in connection with which allergens capable of causing anaphylaxis may be present including, but not limited to, restaurants, recreation camps, youth sports leagues, amusement parks, and sports arenas. "Authorized entity" shall not include any public

school or public charter school;

(3) "Epinephrine auto-injector", a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body;

(4) "Physician", a physician licensed in this state under chapter 334;

(5) "Provide", the supply of one or more epinephrine auto-injectors to an individual;

(6) "Self-administration", a person's discretionary use of an epinephrine auto-injector.

2. A physician may prescribe epinephrine auto-injectors in the name of an authorized entity for use in accordance with this section, and pharmacists, physicians, and other persons authorized to dispense prescription medications may dispense epinephrine auto-injectors under a prescription issued in the name of an authorized entity.

3. An authorized entity may acquire and stock a supply of epinephrine auto-injectors under a prescription issued in accordance with this section. Such epinephrine auto-injectors shall be stored in a location readily accessible in an emergency and in accordance with the epinephrine auto-injector's instructions for use and any additional requirements established by the department of health and senior services by rule. An authorized entity shall designate employees or agents who have completed the training required under this section to be responsible for the storage, maintenance, and general oversight of epinephrine auto-injectors acquired by the authorized entity.

4. An authorized entity that acquires a supply of

epinephrine auto-injectors under a prescription issued in accordance with this section shall ensure that:

(1) Expected epinephrine auto-injector users receive training in recognizing symptoms of severe allergic reactions including anaphylaxis and the use of epinephrine auto-injectors from a nationally recognized organization experienced in training laypersons in emergency health treatment or another entity or person approved by the department of health and senior services;

(2) All epinephrine auto-injectors are maintained and stored according to the epinephrine auto-injector's instructions for use;

(3) Any person who provides or administers an epinephrine auto-injector to an individual who the person believes in good faith is experiencing anaphylaxis activates the emergency medical services system as soon as possible; and

(4) A proper review of all situations in which an epinephrine auto-injector is used to render emergency care is conducted.

5. Any authorized entity that acquires a supply of epinephrine auto-injectors under a prescription issued in accordance with this section shall notify the emergency communications district or the ambulance dispatch center of the primary provider of emergency medical services where the epinephrine auto-injectors are to be located within the entity's facility.

6. No person shall provide or administer an epinephrine auto-injector to any individual who is under eighteen years of age without the verbal consent of a parent or guardian who is

present at the time when provision or administration of the epinephrine auto-injector is needed. Provided, however, that a person may provide or administer an epinephrine auto-injector to such an individual without the consent of a parent or guardian if the parent or guardian is not physically present and the person reasonably believes the individual shall be in imminent danger without the provision or administration of the epinephrine auto-injector.

7. The following persons and entities shall not be liable for any injuries or related damages that result from the administration or self-administration of an epinephrine auto-injector in accordance with this section that may constitute ordinary negligence:

(1) An authorized entity that possesses and makes available epinephrine auto-injectors and its employees, agents, and other trained persons;

(2) Any person who uses an epinephrine auto-injector made available under this section;

(3) A physician that prescribes epinephrine auto-injectors to an authorized entity; or

(4) Any person or entity that conducts the training described in this section.

Such immunity does not apply to acts or omissions constituting a reckless disregard for the safety of others or willful or wanton conduct. The administration of an epinephrine auto-injector in accordance with this section shall not be considered the practice of medicine. The immunity from liability provided under this

subsection is in addition to and not in lieu of that provided under section 537.037. An authorized entity located in this state shall not be liable for any injuries or related damages that result from the provision or administration of an epinephrine auto-injector by its employees or agents outside of this state if the entity or its employee or agent is not liable for such injuries or related damages under the laws of the state in which such provision or administration occurred. No trained person who is in compliance with this section and who in good faith and exercising reasonable care fails to administer an epinephrine auto-injector shall be liable for such failure.

8. All basic life support ambulances and stretcher vans operated in the state shall be equipped with epinephrine auto-injectors and be staffed by at least one individual trained in the use of epinephrine auto-injectors.

9. The provisions of this section shall apply in all counties within the state and any city not within a county.

10. Nothing in this section shall be construed as superseding the provisions of section 167.630.

208.227. **[**Fee for service eligible policies for prescribing psychotropic medications shall not include any new limits to initial access requirements, except dose optimization or new drug combinations consisting of one or more existing drug entities or preference algorithms for SSRI antidepressants, for persons with mental illness diagnosis, or other illnesses for which treatment with psychotropic medications are indicated and the drug has been approved by the federal Food and Drug Administration for at least one indication and is a recognized treatment in one of the

standard reference compendia or in substantially accepted peer-reviewed medical literature and deemed medically appropriate for a diagnosis.] 1. No restrictions to access shall be imposed that preclude availability of any individual atypical antipsychotic monotherapy for the treatment of schizophrenia, bipolar disorder, or psychosis associated with severe depression. The division shall establish a pharmaceutical case management or polypharmacy program for high-risk MO HealthNet participants with numerous or multiple prescribed drugs. The division shall also establish a behavioral health pharmacy and opioid surveillance program to encourage the use of best medical evidence-supported prescription practices. The division shall communicate with providers, as such term is defined in section 208.164, whose prescribing practices deviate from or do not otherwise utilize best medical evidence-supported prescription practices. The communication may be telemetric, written, oral, or some combination thereof. These programs shall be established and administered through processes established and supported under a memorandum of understanding between the department of mental health and the department of social services, or their successor entities.

2. The provisions of this section shall not prohibit the division from utilizing clinical edits to ensure clinical best practices including, but not limited to:

(1) Drug safety and avoidance of harmful drug interactions;

(2) Compliance with nationally recognized and juried clinical guidelines from national medical associations using medical evidence and emphasizing best practice principles;

(3) Detection of patients receiving prescription drugs from multiple prescribers; and

(4) Detection, prevention, and treatment of substance use disorders.

3. The division shall issue a provider update no less than twice annually to enumerate treatment and utilization principles for MO HealthNet providers including, but not limited to:

(1) Treatment with antipsychotic drugs, as with any other form of treatment, should be individualized in order to optimize the patient's recovery and stability;

(2) Treatment with antipsychotic drugs should be as effective, safe, and well-tolerated as supported by best medical evidence;

(3) Treatment with antipsychotic drugs should consider the individual patient's needs, preferences, and vulnerabilities;

(4) Treatment with antipsychotic drugs should support an improved quality of life for the patient;

(5) Treatment choices should be informed by the best current medical evidence and should be updated consistent with evolving nationally recognized best practice guidelines; and

(6) Cost considerations in the context of best practices, efficacy, and patient response to adverse drug reactions should guide antipsychotic medication policy and selection once the preceding principles have been maximally achieved.

4. If the division implements any new policy or clinical edit for an antipsychotic drug, the division shall continue to allow MO HealthNet participants access to any antipsychotic drug that they utilize and on which they are stable or that they have

successfully utilized previously. The division shall adhere to the following:

(1) If an antipsychotic drug listed as "nonpreferred" is considered clinically appropriate for an individual patient based on the patient's previous response to the drug or other medical considerations, prior authorization procedures, as such term is defined in section 208.164, shall be simple and flexible;

(2) If an antipsychotic drug listed as "nonpreferred" is known or found to be safe and effective for a given individual, the division shall not restrict the patient's access to that drug. Such nonpreferred drug shall, for that patient only and if that patient has been reasonably adherent to the prescribed therapy, be considered "preferred" in order to minimize the risk of relapse and to support continuity of care for the patient;

(3) A patient shall not be required to change antipsychotic drugs due to changes in medication management policy, prior authorization, or a change in the payor responsible for the benefit; and

(4) Patients transferring from state psychiatric hospitals to community-based settings, including patients previously found to be not guilty of a criminal offense by reason of insanity or who have previously been found to be incompetent to stand trial, shall be permitted to continue the medication regimen that aided the stability and recovery so that such patient was able to successfully transition to the community-based setting.

5. The division's medication policy and clinical edits shall provide MO HealthNet participants initial access to multiple Food and Drug Administration-approved antipsychotic

drugs that have substantially the same clinical differences and adverse effects that are predictable across individual patients and whose manufacturers have entered into a federal rebate agreement with the Department of Health and Human Services. Clinical differences may include, but not be limited to, weight gain, extrapyramidal side effects, sedation, susceptibility to metabolic syndrome, other substantial adverse effects, the availability of long-acting formulations, and proven efficacy in the treatment of psychosis. The available drugs for an individual patient shall include, but not be limited to, the following categories:

(1) At least one relatively weight-neutral atypical antipsychotic medication;

(2) At least one long-acting injectable formulation of an atypical antipsychotic;

(3) Clozapine;

(4) At least one atypical antipsychotic medication with relatively potent sedative effects;

(5) At least one medium-potency typical antipsychotic medication;

(6) At least one long-acting injectable formulation of a high-potency typical antipsychotic medication;

(7) At least one high-potency typical antipsychotic medication; and

(8) At least one low-potency typical antipsychotic medication.

6. Nothing in subsection 5 of this section shall be construed to require any of the following:

(1) Step therapy or a trial of a typical antipsychotic drug before permitting a patient access to an atypical drug or antipsychotic medication;

(2) A limit of one atypical antipsychotic drug as an open-access, first-choice agent; or

(3) A trial of one of the eight categories of drugs listed in subsection 5 of this section before having access to the other seven categories.

7. The department of social services may promulgate rules and regulations to implement the provisions of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable, and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2017, shall be invalid and void.

8. The department shall submit such state plan amendments and waivers to the Centers for Medicare and Medicaid Services of the federal Department of Health and Human Services as the department determines are necessary to implement the provisions of this section.

9. As used in this section, the following terms mean:

(1) "Division", the MO HealthNet division of the department

of social services;

(2) "Reasonably adherent", a patient's adherence to taking medication on a prescribed schedule as measured by a medication position ratio of at least seventy-five percent;

(3) "Successfully utilized previously", a drug or drug regimen's provision of clinical stability in treating a patient's symptoms.

208.229. 1. Pharmaceutical manufacturers shall pay to the state, in accordance with 42 U.S.C. Section 1396r-8, rebates on eligible utilization of covered outpatient drugs dispensed to MO HealthNet participants under the MO HealthNet pharmacy program as follows:

(1) For single source drugs and innovator multiple source drugs, rebates shall reflect the manufacturer's best price, as defined by 42 CFR 447.505, as updated and amended, and set forth in 42 CFR 447.509, as updated and amended; and

(2) For single source drugs and innovator and noninnovator multiple source drugs, any additional rebates necessary to account for certain price increases in excess of inflation, as set forth in 42 CFR 447.509, as updated and amended.

2. For purposes of this section, the terms "innovator multiple source drug", "noninnovator multiple source drug", and "single source drug" shall have the same meanings as defined in 42 CFR 447.502, as updated and amended.

208.790. 1. The applicant shall have or intend to have a fixed place of residence in Missouri, with the present intent of maintaining a permanent home in Missouri for the indefinite future. The burden of establishing proof of residence within

this state is on the applicant. The requirement also applies to persons residing in long-term care facilities located in the state of Missouri.

2. The department shall promulgate rules outlining standards for documenting proof of residence in Missouri. Documents used to show proof of residence shall include the applicant's name and address in the state of Missouri.

3. Applicant household income limits for eligibility shall be subject to appropriations, but in no event shall applicants have household income that is greater than one hundred eighty-five percent of the federal poverty level for the applicable family size for the applicable year as converted to the MAGI equivalent net income standard. The provisions of this subsection shall only apply to Medicaid dual eligible individuals.

4. The department shall promulgate rules outlining standards for documenting proof of household income.

208.798. The provisions of sections 208.780 to 208.798 shall terminate on August 28, **[**2017**]** 2022.

334.506. 1. As used in this section, "approved health care provider" means a person holding a current and active license as a physician and surgeon under this chapter, a chiropractor under chapter 331, a dentist under chapter 332, a podiatrist under chapter 330, a physician assistant under this chapter, an advanced practice registered nurse under chapter 335, or any licensed and registered physician, chiropractor, dentist, or podiatrist practicing in another jurisdiction whose license is in good standing.

2. A physical therapist shall not initiate treatment for a new injury or illness without a prescription from an approved health care provider.

3. A physical therapist may provide educational resources and training, develop fitness or wellness programs for asymptomatic persons, or provide screening or consultative services within the scope of physical therapy practice without the prescription and direction of an approved health care provider.

4. A physical therapist may examine and treat without the prescription and direction of an approved health care provider any person with a recurring self-limited injury within one year of diagnosis by an approved health care provider or a chronic illness that has been previously diagnosed by an approved health care provider. The physical therapist shall:

(1) Contact the patient's current approved health care provider within seven days of initiating physical therapy services under this subsection;

(2) Not change an existing physical therapy referral available to the physical therapist without approval of the patient's current approved health care provider;

(3) Refer to an approved health care provider any patient whose medical condition at the time of examination or treatment is determined to be beyond the scope of practice of physical therapy;

(4) Refer to an approved health care provider any patient whose condition for which physical therapy services are rendered under this subsection has not been documented to be progressing

toward documented treatment goals after six visits or fourteen days, whichever first occurs;

(5) Notify the patient's current approved health care provider prior to the continuation of treatment if treatment rendered under this subsection is to continue beyond thirty days. The physical therapist shall provide such notification for each successive period of thirty days.

5. The provision of physical therapy services of evaluation and screening pursuant to this section shall be limited to a physical therapist, and any authority for evaluation and screening granted within this section may not be delegated. Upon each reinitiation of physical therapy services, a physical therapist shall provide a full physical therapy evaluation prior to the reinitiation of physical therapy treatment. Physical therapy treatment provided pursuant to the provisions of subsection 4 of this section may be delegated by physical therapists to physical therapist assistants only if the patient's current approved health care provider has been so informed as part of the physical therapist's seven-day notification upon reinitiation of physical therapy services as required in subsection 4 of this section. Nothing in this subsection shall be construed as to limit the ability of physical therapists or physical therapist assistants to provide physical therapy services in accordance with the provisions of this chapter, and upon the referral of an approved health care provider. Nothing in this subsection shall prohibit an approved health care provider from acting within the scope of their practice as defined by the applicable chapters of RSMo.

6. No person licensed to practice, or applicant for licensure, as a physical therapist or physical therapist assistant shall make a medical diagnosis.

7. A physical therapist shall only delegate physical therapy treatment to a physical therapist assistant or to a person in an entry level of a professional education program approved by the Commission **[**for**]** on Accreditation **[**of**]** in Physical **[**Therapists and Physical Therapist Assistant**]** Therapy Education (CAPTE) who satisfies supervised clinical education requirements related to the person's physical therapist or physical therapist assistant education. The entry-level person shall be under **[**on-site**]** the supervision of a physical therapist.

338.700. As used in sections 338.700 to 338.710, the following terms shall mean:

(1) "Board", the Missouri board of pharmacy;

(2) "Department", the Missouri department of health and senior services;

(3) "Program", the RX cares for Missouri program.

338.710. 1. There is hereby created in the Missouri board of pharmacy the "RX Cares for Missouri Program". The goal of the program shall be to promote medication safety and to prevent prescription drug abuse, misuse, and diversion in Missouri.

2. The board, in consultation with the department, shall be authorized to expend, allocate, or award funds appropriated to the board to private or public entities to develop or provide programs or education to promote medication safety or to suppress or prevent prescription drug abuse, misuse, and diversion in the state of Missouri. In no case shall the authorization include,

nor the funds be expended for, any state prescription drug monitoring program including, but not limited to, such as are defined in 38 CFR 1.515. Funds disbursed to a state agency under this section may enhance, but shall not supplant, funds otherwise appropriated to such state agency.

3. The board shall be the administrative agency responsible for implementing the program in consultation with the department. The board and the department may enter into interagency agreements between themselves to allow the department to assist in the management or operation of the program. The board may award funds directly to the department to implement, manage, develop, or provide programs or education pursuant to the program.

4. After a full year of program operation, the board shall prepare and submit an evaluation report to the governor and the general assembly describing the operation of the program and the funds allocated. Unless otherwise authorized by the general assembly, the program shall expire on August 28, 2019.

✓

_____ _____

David Sater David Wood